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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

v.

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., AND RITE AID CORP., *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF IN OPPOSITION

RICHARD ALAN ARNOLD
SCOTT E. PERWIN
KENNY NACHWALTER *ET AL.*
1100 Miami Center
201 South Biscayne Blvd.
Miami, FL 33131
(305) 373-1000

DOUGLAS H. PATTON
DEWSNUP, KING & OLSEN
Suite 2020 Beneficial Tower
36 South State Street
Salt Lake City, UT 84111
(801) 533-0400

Counsel for Kroger Plaintiffs

DANIEL SEGAL
STEVE D. SHADOWEN*
JOSEPH T. LUKENS
MONICA L. REBUCK
HANGLEY ARONCHICK SEGAL & PUDLIN
One Logan Square, 27th Floor
Phildelphia, PA 19103
(215) 568-6200

Counsel for CVS Meridian Plaintiffs

* *Counsel of Record*

184954

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether the courts below properly concluded that it is *per se* unlawful under Section 1 of the Sherman Antitrust Act for a pharmaceutical patentee to pay a competitor $89 million to keep its competing, FDA-approved generic product off the market during the pendency of patent litigation.

CORPORATE DISCLOSURE STATEMENT

Respondent CVS Meridian, Inc. is a wholly owned subsidiary of CVS Corporation.

Respondent Eckerd Corp. is a wholly owned subsidiary of J.C. Penney Co., Inc.

Respondent The Stop and Shop Supermarket Co. is a wholly owned subsidiary of Ahold USA, Inc.

Respondents Rite Aid Corporation, Albertson's, Inc., The Kroger Co., Walgreen Co., and Hy-Vee, Inc. have no parent corporations and there are no publicly traded companies that own 10% or more of their stock.

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This case involves "a multi-million dollar cash payment [by Hoechst Marion Roussel ("HMR")] in consideration for forbearance by Andrx [Pharmaceuticals, Inc. ("Andrx")] from selling on the market a product that it was ready and able to sell at a price lower than that charged by HMR for [its] patented product." Pet. App. at 31a. The United States Court of Appeals for the Sixth Circuit characterized the Agreement between HMR and Andrx ("the Agreement") as "a plain vanilla horizontal agreement to restrain trade," *id.*, that was a *per se* violation of federal antitrust laws. Labels aside, the court considered the regulatory context in which the Agreement arose, analyzed the exclusionary power of HMR's patent, and considered and rejected the procompetitive justifications offered by the defendants. However denominated, the Court of Appeals' analysis was a correct and straightforward application of the settled law of this Court; it does not require review by this Court.

Review should also be denied because (a) the Circuit conflict asserted by Andrx involves only two Courts of Appeals, and cases involving broader issues of the interplay between pharmaceutical patents and antitrust law have not had the appellate and scholarly analysis necessary to a fully-considered review by this Court; (b) the opinion as to which Andrx seeks review is interlocutory; and (c) the type of agreement at issue here is peculiar to the pharmaceutical industry and, due to recent significant legislative changes, is not likely to recur even in that industry.

COUNTER-STATEMENT OF THE CASE

On average, the price of generic drugs is less than half that of their brand-name counterparts. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 31 (July 1998). In 1984, Congress enacted the Hatch-Waxman Act.[1]

1. That Act is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (*codified* as amended at 21 U.S.C. § 355).

"One of [its] primary goals was to increase the availability of lower-cost generic drugs." *Id.* at 27. To expedite the approval process and hence such drugs' availability, the Act allows a manufacturer seeking to market a generic bioequivalent of an FDA-approved drug to file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). Allowed to rely upon the safety and effectiveness data submitted to the FDA by the manufacturer of the pioneer drug, *id.*, the generic manufacturer can substantially shorten the time required to gain approval of the generic bioequivalent.

On September 22, 1995, Andrx filed an ANDA seeking FDA approval to manufacture and market a generic bioequivalent of Cardizem CD. Cardizem CD is a once-a-day prescription drug manufactured and sold by HMR for the treatment of hypertension and angina. Although the patent on the active chemical ingredient in Cardizem CD expired in November 1992, HMR has a patent, issued in November 1995, on the controlled release formulation which it marketed in the United States under the trademark Cardizem CD.

As an ANDA applicant, Andrx was required to make one of four certifications regarding the pioneer drug's patent status. 21 U.S.C. § 355(j)(2)(A)(vii). Andrx filed a "Paragraph IV Certification," certifying that the patent on the Cardizem CD pioneer drug is invalid or would not be infringed by the generic drug. As required by the statute, Andrx notified HMR, the patent owner, of the ANDA filing and Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(B)(i). In response, in January 1996, HMR commenced a patent infringement action against Andrx, thus triggering a statutory 30-month waiting period before the ANDA could receive the FDA's final approval and Andrx could begin selling its generic drug. *See id.* at § 355(j)(5)(B)(iii). The principal issue in that action was whether Andrx's proposed generic drug had dissolution specifications claimed in HMR's patent.

Andrx filed a counterclaim against HMR asserting antitrust and unfair competition claims on the ground that HMR's patent suit was a "sham" – that no reasonable litigant could expect success on the merits of the claim. *See* Pet. App. at 7a. While Andrx asserted that HMR's patent was invalid, the principal thrust of its defense was that its product did not infringe the HMR patent. Pet. App. at 6a-7a. Andrx asserted to the patent court that it would bring its product to the market as soon as it received final FDA approval. Pet. App. at 7a.

On September 17, 1997, the FDA tentatively approved Andrx's generic drug, meaning that the drug would receive final approval upon the expiration of the 30-month stay on July 9, 1998. Andrx in fact received final FDA approval on July 9, 1998 and was therefore authorized to begin selling its generic version of Cardizem CD as of that date. HMR never sought a preliminary injunction to bar Andrx from selling the generic drug. In recent proceedings in this case, the district court has ruled that there is ample evidence that, but for the Agreement between HMR and Andrx, Andrx would in fact have launched its generic product in July 1998. *See In re Cardizem CD Antitrust Litigation,* 99 MDL 1278, Order No. 80, slip op. at 49-50 (E.D. Mich. Nov. 13, 2003) (Edmunds, J.) ("*In re Cardizem,* Order No. 80").

Because Andrx was the first manufacturer to file an ANDA with a Paragraph IV Certification for a generic bioequivalent of Cardizem CD, Andrx received a statutory 180-day period of market exclusivity before other ANDAs for generic versions of the same pioneer drug could be approved by the FDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Congress enacted the 180-day provision specifically in order to create a powerful incentive for generic drug manufacturers to challenge the validity of patents on brand-name pharmaceuticals. *Pharmachemie B.V. v. Barr Labs., Inc.,* 276 F.3d 627, 629 (D.C. Cir. 2002). Until very recent legislative changes (*see infra* section IV), the 180-day period began to run when the first ANDA applicant either began

selling the generic drug or obtained a judgment that the patent is invalid or not infringed, whichever occurred first. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is a valuable commodity that can be sold or waived for substantial consideration, as would happen if, for example, the first-filer was not prepared to launch but a subsequent ANDA filer was. *See, e.g., Granutec, Inc. v. Shalala*, 1998 U.S. App. LEXIS 6685, at *16 (4th Cir. Apr. 3, 1998); *Mylan v. Shalala*, 81 F. Supp. 2d 30, 42 (D.D.C. 2000).[2]

On September 24, 1997, less than 10 days after Andrx received tentative FDA approval for its generic drug, Andrx and HMR entered into the Agreement at issue here. Under the Agreement, Andrx agreed not to market any generic version of Cardizem CD until a final and unappealable judgment of invalidity or non-infringement was entered in the infringement case. Pet. App. at 97a-99a. Thus, in the absence of such a judgment, Andrx agreed not to market a generic version of Cardizem CD (a) even after Andrx received final FDA approval; (b) even after the automatic 30-month prohibition provided by the Hatch-Waxman Act had expired; and (c) even though the district court hearing the patent case, far from granting a preliminary injunction, had not even been asked by HMR to issue one. By its express terms, this contractually mandated delay in marketing the generic drug applied even if the drug infringed no patent right held by HMR. Pet. App. at 99a-100a. The Agreement also barred Andrx from transferring to another generic manufacturer Andrx's right to the 180-day exclusivity. Pet. App. at 99a. The Agreement thus created a "bottleneck" that prevented not only Andrx, but also any other generic manufacturer of Cardizem CD, from coming onto the market.

In exchange for Andrx's promise to keep generic products off the market, HMR agreed to make non-refundable payments

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2. The FDA will respect such transactions in granting final approval to generic manufacturers that otherwise would be excluded from the market. *See, e.g., Granutec, Inc.*, 1998 U.S. App. LEXIS 6685, at *16.

of $40 million per year to Andrx. Pet. App. at 102a. Additionally, HMR agreed to increase the payments retroactively to $100 million per year if Andrx ultimately prevailed in the infringement suit. Pet. App. at 100a–101a. In the Agreement, HMR and Andrx expressly characterized these payments as compensation for Andrx's "lost profits," Pet. App. at 100a–101a, thus acknowledging that, absent the Agreement, Andrx would in fact have entered the market in July 1998; if Andrx would not have entered, there would have been no lost sales on which Andrx lost profits.

Andrx complied fully with the Agreement and did not market the generic drug even after final FDA approval on July 9, 1998. In June 1999, the FTC began an investigation into the Agreement. Private plaintiffs also filed antitrust claims challenging the Agreement. *See, e.g., Kroger Co., et al. v. Hoechst Marion Roussel, Inc., et al.*, No. 99-6533 (S.D. Fla. filed Apr. 26, 1999). Soon thereafter, HMR and Andrx decided to terminate the Agreement. In conjunction with this decision, HMR dismissed its patent infringement suit and paid Andrx, the alleged infringer, an additional $49 million on top of the $40 million that it had already paid. *See* Pet. App. at 18a. This brought the total payment to the pro-rated equivalent of the annual $100 million payment required if Andrx won the patent action. *See* Pet. App. at 101a. In late June 1999, eleven months after receiving final FDA approval, Andrx finally began marketing a generic version of Cardizem CD.

Plaintiffs/Respondents are chain drugstores that are either direct purchasers of Cardizem CD or the assignees of such purchasers.[3] Plaintiffs assert that but for the Agreement and the payment by HMR to Andrx of at least $40 million per year, Andrx would have brought its generic product to market when

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3. The various cases challenging the Agreement were consolidated for pretrial proceedings in the Eastern District of Michigan by the Judicial Panel on Multidistrict Litigation. *In re Cardizem CD Antitrust Litig.*, MDL-1278 (E.D. Mich.) (Edmunds, J.).

it received FDA approval in July 1998 and that it would have done so at a price lower than that of the patented Cardizem CD sold by HMR. The suits allege that the Agreement unlawfully protected HMR from competition not only from Andrx but also from other potential generic competitors because of the 180-day exclusivity "bottleneck." *See* page 4, *supra.*

On May 11, 2000, the United States District Court for the Eastern District of Michigan granted Plaintiffs' motion for partial summary judgment, ruling that the Agreement constituted an illegal market allocation agreement and was *per se* illegal. Pet. App. at 34a-82a. The district court then certified the issue for interlocutory appeal under 28 U.S.C. § 1292(b).

The Sixth Circuit accepted the appeal and affirmed the district court's holding that the Agreement was unlawful. Pet. App. at 20a-21a. Characterizing the Agreement as unlawful *per se*, the Court of Appeals nevertheless conducted a careful analysis of the statutory and regulatory framework, found that the Agreement provided exclusion to HMR beyond that provided by the patent, and considered and rejected each of the procompetitive justifications proffered by the defendants. Pet. App. at 17a-21a.

The district court has subsequently denied Andrx's motion for summary judgment on the issue of whether Andrx's conduct caused injury to Plaintiffs; in doing so, the court found that there is very substantial evidence that, absent the unlawful Agreement, Andrx would in fact have entered the market in July 1998 – eleven months before its actual entry. *In re Cardizem,* Order No. 80, at 49-50. An estimated 3-week trial of the *CVS Meridian* plaintiffs' claims is scheduled to commence on April 12, 2004. *In re Cardizem,* Scheduling Order No. 49 (E.D. Mich. Dec. 3, 2003) (Edmunds, J.).

REASONS FOR DENYING THE PETITION

I. THE PETITION SHOULD BE DENIED BECAUSE THE SIXTH CIRCUIT DECISION REFLECTS THE STRAIGHTFORWARD APPLICATION OF SETTLED PRECEDENT OF THIS COURT.

There is nothing remarkable or even noteworthy about the Court of Appeals' conclusion that it is *per* se unlawful for one competitor to pay another to stay out of the market. The Court concluded that the Agreement is "at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." Pet. App. at 18a. That conclusion is consistent with more than a century of jurisprudence holding agreements between actual or potential competitors to allocate territories or customers to be unlawful *per se* under Section 1 of the Sherman Act. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *United States v. Topco Assoc.*, 405 U.S. 596, 608-09 (1972); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899).

Of course, the Court of Appeals was required to take account of the fact that HMR asserted a right to exclude Andrx's product under the patent law. A patent owner cannot be subject to antitrust liability merely for exercising whatever power is given to him by the patent to exclude others from making, using, or selling his invention. But when the patent owner exercises exclusionary power *beyond* that conferred by the patent, he and his co-conspirators are fully subject to the antitrust law, including, where the nature of the restraint warrants, the *per se* rule. This has been settled law for decades. *See, e.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377-78 (1952); *United States v. United States Gypsum Co.*, 333 U.S. 364, 400-01 (1948); *United States v. Line Material Co.*, 333 U.S. 287, 314-15 (1948); *see also id.* at 319 (Douglas, J., concurring) (when patent owner

agrees on price with competitor, "[h]e then gets not a benefit inherent in the right of exclusion, but a benefit which flows from suppression of competition by combination with his competitors"). And it is consistently recognized as the governing standard today. *See, e.g., Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).

A. *The Court of Appeals' Analysis*

In a straightforward application of these principles, the Court of Appeals held that the Agreement clearly enabled HMR to wield exclusionary power beyond that conferred by the patent.

The patent conferred exclusionary power on HMR in three ways:

- *First*, it gave HMR the ability to exclude generics by filing an infringement suit that triggered the Hatch-Waxman Act's automatic 30-month exclusion. That exclusionary period expired in July 1998 and was simply not in force in the July 1998-June 1999 period during which the Agreement kept Andrx from marketing its generic product.

- *Second*, the patent also gave HMR the ability to seek a preliminary injunction from the patent court. This was a mere threat; Congress did not give patent holders an absolute right to pretrial exclusion. In order to exclude allegedly infringing products during the pendency of an infringement action, a patent holder must satisfy the criteria for entry of a preliminary injunction, including a showing that his patent is likely to be found valid and infringed and that the public will not be harmed. Absent such a showing, the alleged infringer has a "right to compete." *See, e.g., Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (denying preliminary injunction and permitting pretrial entry).

- *Third*, the patent gave HMR the ability to threaten to collect damages against Andrx for pretrial sales if the patent court subsequently found these sales to have been infringing.

This was also a mere threat; Congress gave patent holders a rebuttable, but not conclusive, presumption of validity, and Congress placed the burden on the patent holder to prove infringement.[4] In the 40 Hatch-Waxman cases that have been litigated to final judgment, the generic manufacturer has been found not to have infringed a valid patent in 29 of them. FTC, *Generic Drug Entry Prior to Patent Expiration* at 19-20, (July 2002) (available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

Against that background, the Court of Appeals held that the HMR patent did not create an "'impenetrable' legal impediment to Andrx's production and sale of its FDA-approved generic product." Pet. App. at 31a. Indeed, the Court found that if the "independent durability of [HMR's] patent and the validity

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4. If HMR had simply threatened Andrx with the possibility of an injunction and/or liability for damages, HMR would have been exercising the power inherent in the patent, and there would be no issue of antitrust liability. No one asserts that it is unlawful for patent litigants to settle a patent case based on the strength of the patent as perceived by the litigants. For example, the alleged infringer may exit the market in exchange for the patent holder's waiver of accrued damages, and patent litigants may settle the case by the patent holder granting a license to the alleged infringer. Herbert Hovenkamp, et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1739-42 (2003); Keith Leffler, Christopher Leffler, "*Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*," 2 ABA Economics Committee Newsletter 26, 33 (Spring 2002). In such cases, the patent holder is merely wielding whatever exclusionary power the patent actually confers, and the sole source of the exclusion is the perceived power of the patent.

Andrx's assertion that the FTC staff has sought *per se* condemnation of "delayed licenses" *absent exclusion payments*, Pet. at 15, is simply wrong. The assertion is not supported by Andrx's citations. In fact, the FTC staff has not sought condemnation of delayed licenses *absent exclusion payments* even under the rule of reason. *In re Schering Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Decision, December 8, 2003).

of its infringement claim" had been sufficient on their own to exclude Andrx from the market, then HMR "would not have paid [Andrx] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 32a. Rather than granting to HMR an absolute right to exclusion, the patent law and HMR's patent merely created in Andrx a "fear of damages in the patent infringement litigation," *id.* at 25a, a fear that may or may not have prompted Andrx, acting "unilaterally, and legally [to refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 32a. HMR's payments to Andrx gave to HMR that which the patent law did not; "the Agreement *guaranteed* to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval." *Id.* at 17a-18a (emphasis added).

In short, HMR did not procure Andrx's exclusion from the market merely by exercising the statutorily-approved exclusionary power of the patent. Instead, HMR procured Andrx's exclusion *by adding to that power the extra-statutory exclusionary power of $89 million*. HMR confronted Andrx not only with the "stick" of the power of the patent – the prospect of being subjected to an injunction or having to pay damages – but also with the "carrot" of multimillion-dollar payments. Citing precisely this analysis from the Plaintiffs' brief below, the Court of Appeals succinctly and definitively held: "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Pet. App. at 19a.[5]

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5. In the Agreement, Andrx also agreed to refrain from selling products that did not even arguably infringe HMR's patent. *See* Pet. App. at 99a. As to these plainly non-infringing generic versions of Cardizem CD, HMR had no patent power at all, but rather presented

(Cont'd)

The Court of Appeals noted that, given the obviously anticompetitive nature of the Agreement, the defendants' proffered justifications were irrelevant as a matter of law. Pet. App. at 20a (*citing Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332 (1982)). The Court nevertheless considered and rejected all of the procompetitive justifications offered by HMR and Andrx for their unlawful agreement. Specifically, "the Agreement cannot fairly be characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation." Pet. App. at 19a. The Court noted that the rejection of these procompetitive justifications was "explained in greater detail in the district court's opinion." *Id.* at 18a-19a. (*citing* 105 F. Supp. 2d at 700-05, which is Pet. App. 75a-81a).

For example, the district court rejected the defendants' contention that HMR's payments provided Andrx with capital to invent around the HMR patent and therefore come to market sooner than was otherwise possible. Pet. App. at 78a-79a.

(Cont'd)

Andrx *solely* with the power of $40 million per year. A more naked, blatantly unlawful agreement is hard to imagine. *United States v. United States Gypsum Co.*, 333 U.S. 364, 400 (1948); *Dole Refrig. Co. v. Kold-Hold Mfg. Co.*, 185 F.2d 809, 816 (6th Cir. 1950); *United States v. Crown Zellerbach Corp.*, 141 F. Supp. 118, 126 (N.D. Ill. 1956) ("any attempt to prohibit competition from unpatented goods carries the patentee beyond the immunity of the patent law"); *United States v. National Lead Co.*, 63 F. Supp. 513, 524 (S.D.N.Y. 1945). The Agreement also provided an ironclad guarantee against competition not only from Andrx, but also from *any* generic manufacturer. As noted, the Agreement prohibited Andrx from relinquishing or assigning its 180-day period of exclusivity under the Hatch-Waxman Act, a period which began to run only after the Agreement-delayed date on which Andrx began to market the drug. This Agreement-created "bottleneck" prevented all other generic manufacturers from coming to market with a generic product. Pet. App. at 8a; s*ee also Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1067 (Fed. Cir. 1998); David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food and Drug L. J. 321, 335 (2000).

The Court noted that the Agreement prevented Andrx from coming to market even with the reformulated product that HMR's payments allegedly helped it to produce. *Id.* And although it was unnecessary for the court to reach these issues, we note that defendants did *not* assert that Andrx *needed* to use the payments from HMR, that HMR was the only source of such development funds, or that Andrx needed anywhere near $89 million to create the reformulated product. Indeed, HMR paid Andrx $49 million after Andrx had already reformulated the product. Pet. App. at 9a.

In short, the Court of Appeals conducted a detailed analysis of the Agreement against the relevant statutory and regulatory background, concluded that the $89 million payment allowed HMR to obtain guaranteed pretrial exclusion that neither the patent law nor the Hatch-Waxman Act provided, and considered and rejected each of the procompetitive justifications offered by the defendants. It is irrelevant that the Court of Appeals used the "per se" label to describe its careful analysis, the fact is that the analysis was "meet for the case." *California Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999).

B. *Professor Hovenkamp's Analysis*

Concluding that agreements such as that at issue here should be found "presumptively unlawful," prominent commentators have endorsed the analysis employed by the Court of Appeals here. *See* Hovenkamp, 87 Minn. L. Rev. 1759; Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391, 396-402 (2003). These commentators note that Congress did not, as it might have done, grant to patent holders an automatic right to pretrial exclusion or grant to them a conclusive presumption of validity. The reward actually granted by Congress to patent holders for their innovation is only *some probability* (less than 100%) of being able to exclude competitors. Payments by the patent holder such as those involved in this case bolster the probability of exclusion from something less than 100% to 100%; thus such payments, in

every case, impermissibly add to the exclusionary power of the patent. Professor Hovenkamp explains:

> [A] patent is not a right to exclude, but rather a right to try to exclude. Indeed, a significant number of patents that make it to court are ultimately held invalid or not infringed. The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. **What the pharmaceutical patentees who agree to exclusion payments seek is something more – a guaranteed insulation from competition, without the risk that the patent is held invalid.** [Intellectual property] policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.

Hovenkamp, 87 Minn. L. Rev. at 1761-62 (emphasis added). As is readily apparent, this is the same substantive analysis employed by the Court of Appeals.

C. *The FTC's Analysis*

The same type of analysis was also recently endorsed by a unanimous Federal Trade Commission in *In re Schering-Plough Corporation*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003) ("*In re Schering-Plough*") (page citations are to page numbers available on Westlaw version). While the FTC asserted that its analysis was one conducted under the rule of reason, it readily acknowledged that the label attached to such analysis is largely a question of "semantics" and that what matters is the substance of the analysis actually employed. *Id.* at 9-10 n.17.

Like the Court of Appeals, the FTC began its analysis by observing that neither the patent law nor the Hatch-Waxman Act grants to a patent holder an absolute right to exclusion.

The FTC noted that "antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework." *Id.* at 16. Accordingly,

> We cannot assume that [the patent holder] had a right to exclude . . . generic competition for the life of the patent any more than we can assume that [the generic manufacturer] had the right to enter earlier. In fact, we make neither assumption but rather focus on the effect that [the patent holder's] payment to [the generic manufacturer] was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.

Id. at 17.[6]

The FTC held that common sense and economic theory demonstrate that "the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 15. It held that any substantial payment made by the patent holder is therefore anticompetitive. *Id.*

Like the Court of Appeals in the instant case, the FTC also considered and rejected the defendants' proffer of procompetitive justifications. In particular, the FTC considered a justification that a "'cash-starved' generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer." *Id.* at 19. The FTC ruled that such a justification cannot be accepted unless the defendants "explain why the [patent holder] was the best source for the necessary funds; [and] demonstrate that the up-front support actually resulted in an entry date earlier than would be expected without it." *Id.* at 20. The FTC noted that, in any event, such an alleged procompetitive justification "could not

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6. "We focus on the state of the world as it was perceived by the parties at the time that they entered into the settlement agreement, when they could not be sure how the litigation would turn out." *Id.* at 18.

justify a payment of any amount close to the $60 million." *Id.* at 20. *A fortiori*, such a proffered procompetitive benefit could not justify the $89 million payment at issue here.

Like the Court of Appeals, the FTC fired a shot across the bow of others that may be considering exclusion payments. The FTC held that in future cases the Commission may apply a "more truncated analysis," *id.* at 20, and seek disgorgement of profits, *id.* at 41 n.113.

The FTC's decision does include one additional strand of analysis that is absent from the Court of Appeals' decision. The FTC began its analysis by finding as a fact that the patent holder had market power. *Id.* at 11-15. It was perhaps appropriate for the FTC, as an administrative agency examining the issue for the first time, to engage in a detailed analysis of market power. The reality, however, is that it is obvious that a patent holder will not pay a generic manufacturer to refrain from entering the market unless the patent holder in fact has market power. *See* Hovenkamp, 87 Minn. L. Rev. at 1757-58; *see also* Robert Bork, *The Antitrust Paradox*, 269 (Free Press 1993) ("Very few firms that lack power to affect market prices will be sufficiently foolish to enter into conspiracies to fix prices. The fact of agreement defines the market."). If a patent does not confer upon its holder the ability to charge an above-competitive price, the patent holder has no reason to pay a potential competitor to refrain from entering the market; entry of an additional competitor will not have any effect on the market price. Thus, despite the fact that the FTC conducted a market power inquiry and the Court of Appeals did not, such an inquiry is entirely unnecessary on the facts as presented here.

* * * * *

The analyses of the Sixth Circuit, Professor Hovenkamp, and the FTC each conclude that payments by the patent holder to the potential generic entrant are unlawful because neither the

patent law nor the Hatch-Waxman Act grants to patent holders a right to automatic exclusion. By making substantial payments to a potential entrant to refrain from entering, the patent holder obtains exclusion beyond that provided by the patent or the regulatory framework. Absent procompetitive justifications – and there are none here that are valid – agreements embodying such payments are unlawful under the Sherman Act.

That conclusion is particularly clear with respect to a pharmaceutical patent holder's right to *pretrial* exclusion. In the Hatch-Waxman Act, Congress granted to holders of such patents 30 months of guaranteed exclusion pending resolution of a lawsuit initiated by the patent holder. 21 U.S.C. § 355(j)(5)(B)(iii). This automatic exclusion – which in original versions of the legislation was for only 18 months – was part of the complex balancing by Congress between the rights of patent holders and those of consumers and generic manufacturers. *See* Alfred Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 398-407 (1999) (reviewing legislative history). Congress expressly withheld automatic exclusion when the patent holder failed to meet the statutory criteria or when the 30 months expired. On what conceivable basis could an antitrust court then permit the patent holder to pay his competitor, as HMR paid Andrx, for exclusion in months 31 to 42?

Of course, the patent court might have subsequently found Andrx's pretrial generic sales to have been infringing. This Court, however, has rejected attempts to justify cartels on the ground that they were necessary to suppress "illegal" competition. *See, e.g., FTC v. Ind. Fed. of Dentists*, 476 U.S. 447, 465 (1986) ("That a particular practice may be unlawful is not, in itself, a sufficient justification for collusion among competitors to prevent it"); *Fashion Orig. Guild, Inc. v. FTC*, 312 U.S. 457, 468 (1941) (prevention of illegal competition is no defense to Section 1 claim). If competition that is *concededly* illegal is still protected by the antitrust laws, then competition

that is only *possibly* illegal – competition in the shadow of potential patent infringement liability – is even more clearly entitled to that same protection. As noted by Professor Shapiro, "Congress should set the rules governing what type of competition is permitted in the shadow of patent litigation and then private firms should live within those rules. Competitors should not be permitted to enter into private agreements that eliminate competition otherwise permitted by Congress." Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 Antitrust 70, 73 (2003).[7]

II. THE PETITION SHOULD BE DENIED IN ORDER TO AWAIT FURTHER CONSIDERATION OF THE ISSUE BY OTHER LOWER COURTS AND SCHOLARS.

Pointing to the Eleventh Circuit's decision in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), Andrx asserts that there is a "split in the circuits" that justifies review by this Court. Pet. at 1. But the split is between only the Sixth and Eleventh Circuit decisions, both of which were rendered on interlocutory review. Moreover, even the conflict between those two Courts is over a very narrow point.

Both Courts agree that: (1) the proper antitrust inquiry is whether the patent holder exceeded the exclusionary power of the patent; *see* Pet. App. at 19a and 148a-149a, and (2) the first step in that analysis is to determine the nature and scope of the exclusionary right actually granted by Congress in the patent law. *See* Pet. App. at 19a and 149a. The Courts' analyses (and conclusions) diverge because the Sixth Circuit carefully delineated the precise nature of a patent holder's right to pretrial exclusion of allegedly infringing competition.

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7. Thus, contrary to Andrx's assertion, Pet. at 24, the Court of Appeals' decision does not "promote infringing competition." When neither the Hatch-Waxman Act nor a preliminary injunction prohibits competition, the Court's decision appropriately protects competition that is merely *alleged* to be infringing.

See Pet. App. at 19a. The Eleventh Circuit did not; its *entire* analysis on the critical first step consisted of the bald and oversimplified assertion that "a patent grants its owner the lawful right to exclude others." Pet. App. at 133a. The Eleventh Circuit did not consider the significance of the fact that the patent law does *not* grant an absolute right to a preliminary injunction. Nor did the Eleventh Circuit address the fact that Congress in the Hatch-Waxman Act expressly limited the right to automatic exclusion to 30 months.

Given the Eleventh Circuit's erroneous delineation of a patent holder's right to pretrial exclusion,[8] it is unsurprising that the Court held that the patent holder's payment was not necessarily beyond the exclusionary power of the patent. Pet. App. at 135a-136a. *If*, arguendo, a patent granted an *absolute* right to pretrial exclusion, then the antitrust laws should indeed be indifferent to the fact that the patent holder was foolish enough to pay for that to which he was already absolutely entitled.

It is highly unlikely that another court of appeals will make the fundamental error committed by the Eleventh Circuit. Indeed, this case and the Eleventh Circuit case are the only pending cases involving payments to preclude *pretrial* competition. All of the other pending cases involve exclusion payments made in connection with *final settlement* of patent litigation. *See, e.g., In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003); *In re Schering-Plough,* FTC Docket No. 9297. Thus, none of those cases will involve the issue that divided the

8. The Court's consequently flawed antitrust analysis is not different in kind from a court's announcement that because a patent "grants its owner the lawful right to exclude others," the holder may lawfully pay a competitor to stay out of the market in years 21 and 22 – even though a *properly delineated* "right to exclude" shows that the temporal scope of the patent is only 20 years. It is simply not enough to say that a patent grants a "right to exclude;" a proper antitrust analysis depends upon a correct understanding of the nature and contours of that right.

Sixth and Eleventh Circuits – the proper delineation of the right to *pretrial* exclusion under the patent law.

To the extent that other pending cases involve the broader general issue of the proper interplay between patent and antitrust law in the pharmaceutical arena, the federal courts are only now beginning to develop a body of law on the appropriate antitrust analysis. Even if the issue is ultimately deemed important enough to be addressed by this Court, the Court should have in front of it the fully developed analysis of the appellate courts. At the moment, that analysis simply is not complete.

For instance, in the most procedurally advanced case, *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), appeal pending, No. 03-7641 (2d Cir. June 20, 2003),[9] the patent holder both made a relatively modest payment ($21 million) and granted the generic manufacturer a 9-year license to bring a cheaper version of the branded drug onto the market. The district court held that plaintiffs had not alleged that, absent the $21 million payment, the license terms would have been any more favorable to consumers. *Id.* at 136-37. The district court therefore dismissed the antitrust complaint for, among other things, failure to allege antitrust injury. *Id.* at 137-38. Thus, on review, the Court of Appeals may not even reach the question whether the agreement was unlawful.

Another case from the Second Circuit, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), may ultimately yield a more complete court of appeals analysis because the exclusion payment there was $398 million and the district court has required the parties to present a full rule of reason analysis. *Id.* at 257-58. But discovery in that case has only recently closed and motions for summary judgment are not due until May 28, 2004.

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9. The opening brief has not yet been filed in the Court of Appeals.

The very recent FTC decision in *In re Schering-Plough Corp.* will presumably be appealed to a court of appeals. Depending on the relative pace of review, an appellate decision could be issued roughly contemporaneously with that of the Sixth Circuit after the April 12, 2004 trial scheduled in this case.[10]

Contrary to Andrx's suggestion, Pet. at 13, the current activity in the federal courts on these issues strongly supports denying the Petition. Because there are only two pending cases involving payments for pretrial exclusion, review by this Court is not warranted at all. To the extent that these two cases are part of a larger debate that includes the propriety of payments for *final* exclusion, review at this time would be premature. The latter issues have not yet been examined at the appellate level, and this Court should consider those courts' perspectives if it ultimately reviews the issue. "The more important an issue is, the more the Court would benefit by allowing the issue to percolate so it can avail itself of the wisdom of other courts before settling a momentous matter." Robert L. Stern, Eugene Gressman, et al., *Supreme Court Practice*, at 457 (8th Ed. 2002).

Forgoing review at this time would also allow for scholarly debate on the issue. Although several articles have examined the question of the proper analysis of exclusion payments in the pharmaceutical industry, *see* Pet. at 28-29, none has addressed the very recent split between the Sixth and Eleventh Circuits. Professor Hovenkamp's extensive analysis of these issues was

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10. Another case cited by Andrx is *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003), but the court there expressly noted that the case did *not* involve exclusion payments. *Id.* at *6. Although the court mused in dicta about the wisdom of a *per se* ban on such payments, it noted that "in fact there is a difference between the reverse payment case and other forms of settlement. In a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market. In this case, in contrast, the settlement led to increased competition." *Id.*

published only in June 2003. Nor have scholars yet had any opportunity to analyze the FTC's extensive decision, issued only two weeks ago. This Court is entitled to the benefit of a full scholarly debate before addressing these issues.

Also worth noting in the context of maximizing the number of perspectives before the Court is the fact that the only defendant in this case is the generic company, Andrx. The owner of the relevant patent, HMR, has settled and is no longer a party to this litigation. Yet patentees obviously have an enormous stake in the issues. By contrast, the other currently pending cases include as active litigants not only the generic company but also the brand company that made the exclusion payment.

III. THE PETITION SHOULD BE DENIED BECAUSE THE SIXTH CIRCUIT RULING WAS ON AN INTERLOCUTORY APPEAL.

This Court has long recognized that interlocutory decisions such as that at issue here are generally inappropriate candidates for certiorari. "This Court should not issue a writ of certiorari to review a decree of the Circuit Court of Appeals on appeal from an interlocutory order, unless it is necessary to prevent extraordinary inconvenience and embarrassment in the conduct of the cause." *American Construction Co. v. Jacksonville, T. & K. W. Railway Co.*, 148 U.S. 372, 384 (1893); *see also Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916) ("Except in extraordinary cases, the writ is not issued until final decree"); *Brotherhood of Locomotive Firemen v. Bangor & Aroostock R. Co.*, 389 U.S. 327, 328 (1967) (denying certiorari "[b]ecause the Court of Appeals remanded the case, it is not yet ripe for review by this Court"); *Virginia Military Institute v. United States*, 508 U.S. 946 (1993) (Scalia, J., concurring in the denial of certiorari noting that the Court will "generally await final judgment in a lower court before exercising our certiorari jurisdiction"). Andrx does not and cannot point to any "extraordinary inconvenience or

embarrassment" justifying any departure from this Court's reluctance to review interlocutory decisions.

The specific posture of this case graphically demonstrates the wisdom of that reluctance in two ways. First, Andrx's own argument demonstrates the inappropriateness of the interlocutory review that it seeks. Andrx contends that, in order to determine whether the Agreement is unlawful, a court must first determine whether the Agreement had an actual anticompetitive effect. *See* Pet. at 22-23. By this, Andrx means that a court must first determine whether, absent the Agreement, Andrx in fact would have entered the market earlier. *Id.* at 23.

The district court, here, however, has already held that there is a disputed issue of material fact – to be resolved at the trial set for April 12, 2004 – as to whether Andrx would have entered earlier absent the exclusion payments. In denying summary judgment to Andrx on this issue, the court explicitly ruled that there is substantial evidence in this record from which a jury could conclude that Andrx in fact would have come to market earlier. *In re Cardizem,* Order No. 80, at 49-50. Therefore, the very rule that Andrx urges this Court to adopt – that the Agreement is not unlawful unless Andrx would in fact have entered – has embedded in it a factual dispute that has not yet been resolved. Review by this Court of the interlocutory decision is accordingly premature. The existence of an unresolved fact central to a party's analysis counsels strongly in favor of the denial of certiorari.

Second, interlocutory review is also inappropriate here because this case, if allowed to proceed to final judgment, may be resolved on grounds that moot the entire question of the proper mode of analysis. Causation is a central issue remaining to be decided in this case. If Plaintiffs fail to prove at trial that Andrx would have entered earlier absent the Agreement, then Andrx caused Plaintiffs no injury regardless of whether Andrx violated the law. The issue raised by Andrx in its Petition would be moot.

Moreover, numerous decisions of significance have been entered, and will be made before, during, and after trial, by the district court before final judgment. Other decisions in these cases may ultimately merit review by this Court. Thus, granting certiorari in this case now might result in piecemeal review. Much efficiency would be gained at little cost by considering review of any relevant issues together and only after a final judgment is rendered.

IV. THE PETITION SHOULD BE DENIED BECAUSE THE TYPE OF AGREEMENT AT ISSUE IS PECULIAR TO THE PHARMACEUTICAL INDUSTRY AND, EVEN WITHIN THAT INDUSTRY, IS NOT LIKELY TO RECUR.

A. *The Type of Agreement at Issue Here Is Peculiar to the Pharmaceutical Industry.*

Contrary to Andrx's contention (Pet. at 25), the type of exclusion payment at issue in this case is peculiar to the pharmaceutical industry. Such payments are essentially unheard of in any other industry. This is so because it is the pharmaceutical industry's peculiar regulatory scheme under the Hatch-Waxman Act – in particular the 180-day exclusivity period for the first ANDA filer – that provides the necessary structure for these exclusion payments. *See* Hovenkamp, 87 Minn. L. Rev. at 1757.

The first generic manufacturer that files an ANDA with a Paragraph IV Certification is entitled to a 180-day period of exclusivity before the FDA can approve any other manufacturer's ANDA for the same product. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Under the law as it existed at the time of the events giving rise to this and similar cases, the 180-day period did not begin to run until (1) a court found the generic product not to infringe the patent; or (2) the first-filer began commercial marketing of the product, whichever is earlier. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I-II) (1998). The patent holder's payment to

the first-filer to delay commercial marketing could therefore prevent *all* generic manufacturers from entering the market until a court decision concerning infringement.

As Professor Hovenkamp has noted, it is this unique regulatory scheme that resulted in the rash of pharmaceutical cases involving exclusion payments:

> Exclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments. Undoubtedly, what has increased their attraction under that statute is the fact – *unique to pharmaceutical patents* – that a properly defined settlement-plus-exit-payment keeps not only the immediate infringement defendant out of the market for a time, but also [through the 180 day exclusivity period] keeps other generic firms from entering as well.

Hovenkamp, 87 Minn. L. Rev. at 1757 (citations omitted) (emphasis added).

These exclusion payment agreements do not exist in other industries because, without such unique regulatory barriers, a payment to exclude one potential competitor could not result in the exclusion of all other potential competitors. A patent holder who made an exclusion payment to one competitor would be immediately confronted with the need to make similar payments to all other potential competitors. Without a unique entry barrier such as the Hatch-Waxman 180-day exclusivity, making a payment to one competitor is simply not worthwhile.[11]

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11. Andrx's suggestion that the Sixth Circuit's ruling has caused a decline in pharmaceutical innovation (Pet. at 26) – *i.e.*, the development of new drugs – is preposterous. The Pink Sheet article to which Andrx cites connects the decline in IND filings not to any court ruling, but to an overall decline in R&D productivity. *IND Filings Hit Seven-Year Low: Where is R&D Productivity*, Prescription Pharma. & Biotechnology ("The Pink Sheet") 8 (Nov. 10, 2003). Since the late 1980's, real

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B. ***The Types Of Agreements At Issue Here Are Unlikely To Recur Because Recent Significant Legislative Changes To The Hatch-Waxman Scheme And Aggressive Enforcement Actions By The FTC Have Virtually Eliminated The Incentive For Exclusion Payments.***

Not only are exclusion payments unheard of in other industries, they may also be a thing of the past in the pharmaceutical industry. As noted, the major incentive for exclusion payments is the bottleneck that such payments create under the 180-day exclusivity provision of the Hatch-Waxman Act. Recent legislative changes to the Hatch-Waxman scheme and aggressive FTC enforcement have virtually eliminated any incentives to continue to enter into such payment agreements. Without such incentives, these agreements will likely disappear from the landscape regardless of whether the Court grants review of the Sixth Circuit's decision.

As to legislative changes, on December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003, P.L. No.

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innovation in the pharmaceutical industry has been on the decline, with the industry focused more on bringing to market "me-too drugs" (newer versions of older profitable drugs) than new drugs that are truly innovative. *See* National Institute for Health Care Management, Changing Patterns of Pharmaceutical Innovation, at 2 (2002) (of the 1,035 drugs approved by the FDA from 1989 to 2000, only 361, or 35%, contained new active ingredients) (available at http://www.nihcm.org/innovations.pdf). At this same time, pharmaceutical manufacturers' spending on R&D has increased. As the brand companies' trade association, Pharmaceutical and Research Manufacturers of America ("PhRMA"), recently reported: "[I]n 2002, both U.S.-owned and foreign-owned PhRMA member companies invested an estimated $32 billion in R&D. This amount represents a 7.7 percent increase over expenditures in 2001 and is more than triple the investment in 1990." Pharmaceutical Industry Profile, 2003, at 10, PhRMA (available at http://www.phrma.org/publications/publications/profile02/2003%20CHAPTER%202.pdf.).

108-173. This legislation strips the first ANDA filer of its 180-day exclusivity period if it fails to exercise its right to come to market in a timely fashion. P.L. No. 108-173, § 1102. Failure to come to market within 75 days of a qualifying court judgment *or settlement* will cause the total forfeiture of the generic company's 180-day exclusivity period. The amendment thereby eliminates the patent holder's ability to use an exclusion payment to the first ANDA filer to block entry of all other generic companies. The specific purpose of such a provision is to make exclusion payments ineffectual. *See* Prepared Statement of The Federal Trade Commission, Before the Committee on Judiciary, United States Senate, Washington, D.C. (Statement of Chairman Muris, August 1, 2003) (available at http://www.ftc.gov/os/2003/08/030801pharmtest.htm).

This legislative corrective has been coupled with aggressive FTC challenges to exclusion payment agreements. In connection with settling a challenge to such an agreement, the Commissioners announced on March 16, 2000 that: "[p]harmaceutical firms should now be on notice, ... that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm." *Abbott Labs. and Geneva Pharms.*, Docket No. C-3945 (2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary) ("FTC Commissioners' Statement") (available at *http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm*). The FTC Commissioners made clear that "in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits." *Id.* Indeed, since the FTC began its study of these agreements, not a single similar exclusion payment agreement has been entered into by any pharmaceutical manufacturer. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at viii (July 2002), *available at http:/*

/www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The continuously looming threat of a disgorgement remedy has likely put an end to the use of exclusion payments in the pharmaceutical industry. There is therefore little reason for the Court to reach out and review the Sixth Circuit decision.

CONCLUSION

In spite of the absence of full appellate and scholarly development of the relevant issues, Andrx has sought interlocutory review of a unique type of agreement that is highly likely to disappear from the pharmaceutical industry landscape. For the reasons stated above, Andrx's Petition to review the Sixth Circuit's straightforward application of settled law should be denied.

Respectfully submitted,

DANIEL SEGAL
STEVE D. SHADOWEN*
JOSEPH T. LUKENS
MONICA L. REBUCK
HANGLEY ARONCHICK SEGAL & PUDLIN
One Logan Square, 27th Floor
Phildelphia, PA 19103
(215) 568-6200

Counsel for CVS Meridian Plaintiffs

RICHARD ALAN ARNOLD
SCOTT E. PERWIN
KENNY NACHWALTER *ET AL.*
1100 Miami Center
201 South Biscayne Blvd.
Miami, FL 33131
(305) 373-1000

DOUGLAS H. PATTON
DEWSNUP, KING & OLSEN
Suite 2020 Beneficial Tower
36 South State Street
Salt Lake City, UT 84111
(801) 533-0400

Counsel for Kroger Plaintiffs

* *Counsel of Record*